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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

R. DUDLEY

SERIAL NUMBER: 10/046,454

FILED: OCTOBER 19, 2001

TITLE: PHARMACEUTICAL
COMPOSITION AND METHOD
FOR TREATING
HYPOGONADISM

)
) GROUP ART UNIT: 1617
)

)
) EXAMINER: Unassigned
)

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PRELIMINARY AMENDMENT

Assistant Commissioner of Patents
Washington, D. C. 20231

Dear Sir:

Prior to examination of this application, Applicant respectfully requests entry of the
following amendment. If there are any additional fees due in connection with the filing of this
Preliminary Amendment, please charge these additional fees (or credit any overpayment)
associated with this communication to our Deposit Account No. 13-0019.

IN THE SPECIFICATION

To correct several typographical and other errors, please amend the specification as
follows:

Please replace the paragraph beginning on page 15, line 1, with the following rewritten paragraph:

-- FIG. 1 is a graph of testosterone concentrations (\square), DHT concentrations (\bullet), and the DHT/T ratio for patients receiving a subdermal testosterone pellet implant over a period of 300 days after implantation. --

Please replace the paragraph beginning on page 15, line 7, with the following rewritten paragraph:

-- FIG. 3 is a 24-hour testosterone pharmacokinetic profile for patients receiving the TESTODERM[®] TTS patch (\blacksquare), as compared to baseline testosterone serum concentration levels (\bullet). --

Please replace the paragraph beginning on page 15, line 11, with the following rewritten paragraph:

-- FIG. 5(a) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men prior to receiving 5.0 g/day of AndroGel[®] (- - -), 10.0 g/day of AndroGel[®] (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 15, line 14, with the following rewritten paragraph:

-- FIG. 5(b) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on the first day of treatment with either 5.0 g/day of AndroGel[®] (- - -), 10.0

g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 15, line 17, with the following rewritten paragraph:

-- FIG. 5(c) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 30 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 15, line 20, with the following rewritten paragraph:

-- FIG. 5(d) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 90 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 16, line 1, with the following rewritten paragraph:

-- FIG. 5(e) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 180 of treatment with either 5.0 g/day of AndroGel® (- - - -), 7.5 g/day of AndroGel® (— - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by

final treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 4, with the following rewritten paragraph:

-- FIG. 5(f) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (■), 90 (— - -), and 180 (——) of treatment with 5.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 6, with the following rewritten paragraph:

-- FIG. 5(g) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (■), 90 (— - -), and 180 (——) of treatment with 10.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 8, with the following rewritten paragraph:

-- FIG. 5(h) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (■), 90 (— - -), and 180 (——) of treatment with the testosterone patch. Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 10, with the following rewritten paragraph:

-- FIG. 6(a) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 1 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 16, line 13, with the following rewritten paragraph:

-- FIG. 6(b) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 30 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 16, line 16, with the following rewritten paragraph:

-- FIG. 6(c) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 90 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 16, line 19, with the following rewritten paragraph:

-- FIG. 6(d) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 180 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 16, line 22, with the following rewritten paragraph:

-- FIG. 6(e) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 5.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 1, with the following rewritten paragraph:

-- FIG. 6(f) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 10.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 3, with the following rewritten paragraph:

-- FIG. 6(g) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - -), 1 (— —), 30 (—), 90 (— - -), and 180 (—) of treatment with the testosterone patch. Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 5, with the following rewritten paragraph:

-- FIG. 7 is a graph showing the DHT concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 8, with the following rewritten paragraph:

-- FIG. 8 is a graph showing the DHT/T ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 11, with the following rewritten paragraph:

-- FIG. 9 is a graph showing the total androgen concentrations (DHT +T) on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - -), 10.0 g/day of

AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 14, with the following rewritten paragraph:

-- FIG. 10 is a graph showing the E₂ concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 17, with the following rewritten paragraph:

-- FIG. 11 is a graph showing the SHBG concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 20, with the following rewritten paragraph:

-- FIG. 12(a) is a graph showing the FSH concentrations on days 0 through 180 for men having primary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 1, with the following rewritten paragraph:

-- FIG. 12(b) is a graph showing the FSH concentrations on days 0 through 180 for men having secondary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 4, with the following rewritten paragraph:

-- FIG. 12(c) is a graph showing the FSH concentrations on days 0 through 180 for men having age-associated hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 7, with the following rewritten paragraph:

-- FIG. 12(d) is a graph showing the FSH concentrations on days 0 through 180 for men having hypogonadism of an unknown origin and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 10, with the following rewritten paragraph:

-- FIG. 13(a) is a graph showing the LH concentrations on days 0 through 180 for men having primary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 13, with the following rewritten paragraph:

-- FIG. 13(b) is a graph showing the LH concentrations on days 0 through 180 for men having secondary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 16, with the following rewritten paragraph:

-- FIG. 13(c) is a graph showing the LH concentrations on days 0 through 180 for men having age-associated hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 19, with the following rewritten paragraph:

-- FIG. 13(d) is a graph showing the LH concentrations on days 0 through 180 for men having hypogonadism of an unknown origin and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 19, line 1, with the following rewritten paragraph:

-- FIG. 14(a) is a bar graph showing the change in hip BMD for hypogonadal men after 180 days of treatment with 5.0 g/day of AndroGel® (☒), 5.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (wide hatch mark), 10.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (narrow hatch marks), 10.0 g/day of AndroGel® (■), or the testosterone patch (□). --

Please replace the paragraph beginning on page 19, line 4, with the following rewritten paragraph:

-- FIG. 14(b) is a bar graph showing the change in spine BMD for hypogonadal men after 180 days of treatment with 5.0 g/day of AndroGel® (☒), 5.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (wide hatch mark), 10.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (narrow hatch marks), 10.0 g/day of AndroGel® (■), or the testosterone patch (□). --

Please replace the paragraph beginning on page 19, line 7, with the following rewritten paragraph:

-- FIG. 15 is a graph showing PTH concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (—

—), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 19, line 10, with the following rewritten paragraph:

-- FIG. 16 is a graph showing SALP concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— — —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 19, line 13, with the following rewritten paragraph:

-- FIG. 17 is a graph showing the osteocalcin concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— — —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 19, line 16, with the following rewritten paragraph:

-- FIG. 18 is a graph showing the type I procollagen concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— — —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 19, line 19, with the following rewritten paragraph:

-- FIG. 19 is a graph showing the N-telopeptide/Cr ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 20, line 1, with the following rewritten paragraph:

-- FIG. 20 is a graph showing the Ca/Cr ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 21, line 7, with the following rewritten paragraph:

-- FIG. 24(a) is a bar graph showing the change in leg strength on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 10, with the following rewritten paragraph:

-- FIG. 24(b) is a bar graph showing the change in arm strength on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 13, with the following rewritten paragraph:

-- FIG. 25(a) is a bar graph showing the change in total body mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 16, with the following rewritten paragraph:

-- FIG. 25(b) is a bar graph showing the change in lean body mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□). --

Please replace the paragraph beginning on page 21, line 19, with the following rewritten paragraph:

-- FIG. 25(c) is a bar graph showing the change in fat mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (☐). --

Please replace the paragraph beginning on page 22, line 1, with the following rewritten paragraph:

-- FIG. 25(d) is a bar graph showing the change in percent body fat on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (☒), or the testosterone patch (☐). --

2025-04-20 10:54:07

REMARKS

Applicant respectfully submits that no new matter has been added to the specification by these amendments. Support for each amendment can be found in each respective Figure as originally filed.

Also submitted herewith, on a separate appended page titled "Version with Marking to Show Changes Made in the Specification," is a marked up copy of the changes made to the specification.

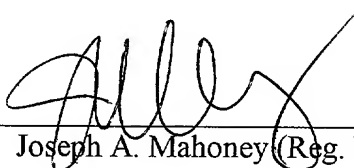
The Examiner is urged to call the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

UNIMED PHARMACEUTICALS, INC.,

By: MAYER, BROWN, ROWE & MAW

By:



Joseph A. Mahoney (Reg. No. 38,956)

Dated: April 5, 2002

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Version with Markings to Show Changes Made

In the Specification

The paragraph beginning on page 2, line 22 has been replaced with the following rewritten paragraph:

Please replace the paragraph beginning on page 15, line 1, with the following rewritten paragraph:

-- FIG. 1 is a graph of testosterone concentrations (\square), DHT concentrations (\bullet), and the DHT/T ratio for patients receiving a subdermal testosterone pellet implant over a period of 300 days after implantation. --

Please replace the paragraph beginning on page 15, line 7, with the following rewritten paragraph:

-- FIG. 3 is a 24-hour testosterone pharmacokinetic profile for patients receiving the TESTODERM[®] TTS patch (\blacksquare), as compared to baseline testosterone serum concentration levels (\bullet). --

Please replace the paragraph beginning on page 15, line 11, with the following rewritten paragraph:

-- FIG. 5(a) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men prior to receiving 5.0 g/day of AndroGel[®] (- - -), 10.0 g/day of AndroGel[®] (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - —) line. --

Please replace the paragraph beginning on page 15, line 14, with the following rewritten paragraph:

-- FIG. 5(b) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on the first day of treatment with either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 15, line 17, with the following rewritten paragraph:

-- FIG. 5(c) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 30 of treatment with either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 15, line 20, with the following rewritten paragraph:

-- FIG. 5(d) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 90 of treatment with either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 16, line 1, with the following rewritten paragraph:

-- FIG. 5(e) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 180 of treatment with either 5.0 g/day of AndroGel® (- - - -), 7.5 g/day of AndroGel® (— - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by final treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 16, line 4, with the following rewritten paragraph:

-- FIG. 5(f) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 5.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 16, line 6, with the following rewritten paragraph:

-- FIG. 5(g) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 10.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 16, line 8, with the following rewritten paragraph:

-- FIG. 5(h) is a graph showing the 24-hour testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (—), 90 (— - -), and 180 (—) of treatment with the testosterone patch. Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 16, line 10, with the following rewritten paragraph:

-- FIG. 6(a) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 1 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 16, line 13, with the following rewritten paragraph:

-- FIG. 6(b) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 30 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (—) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 16, line 16, with the following rewritten paragraph:

-- FIG. 6(c) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 90 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day

of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 19, with the following rewritten paragraph:

-- FIG. 6(d) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 180 of treatment with either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 16, line 22, with the following rewritten paragraph:

-- FIG. 6(e) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 5.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 17, line 1, with the following rewritten paragraph:

-- FIG. 6(f) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (- - - -), 1 (— —), 30 (——), 90 (— - -), and 180 (——) of treatment with 10.0 g/day of AndroGel®. Normal high and low testosterone levels (ng/dl) are represented by the (— - - - -) line. --

Please replace the paragraph beginning on page 17, line 3, with the following rewritten paragraph:

-- FIG. 6(g) is a graph showing the 24-hour free testosterone pharmacokinetic profile for hypogonadal men on day 0 (---), 1 (— —), 30 (■), 90 (— - -), and 180 (——) of treatment with the testosterone patch. Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 5, with the following rewritten paragraph:

-- FIG. 7 is a graph showing the DHT concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 8, with the following rewritten paragraph:

-- FIG. 8 is a graph showing the DHT/T ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - -) line. --

Please replace the paragraph beginning on page 17, line 11, with the following rewritten paragraph:

-- FIG. 9 is a graph showing the total androgen concentrations (DHT +T) on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 14, with the following rewritten paragraph:

-- FIG. 10 is a graph showing the E₂ concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 17, with the following rewritten paragraph:

-- FIG. 11 is a graph showing the SHBG concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 17, line 20, with the following rewritten paragraph:

-- FIG. 12(a) is a graph showing the FSH concentrations on days 0 through 180 for men having primary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 1, with the following rewritten paragraph:

-- FIG. 12(b) is a graph showing the FSH concentrations on days 0 through 180 for men having secondary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 4, with the following rewritten paragraph:

-- FIG. 12(c) is a graph showing the FSH concentrations on days 0 through 180 for men having age-associated hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 7, with the following rewritten paragraph:

-- FIG. 12(d) is a graph showing the FSH concentrations on days 0 through 180 for men having hypogonadism of an unknown origin and receiving either 5.0 g/day of AndroGel® (- - - -),

10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group).

Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 10, with the following rewritten paragraph:

-- FIG. 13(a) is a graph showing the LH concentrations on days 0 through 180 for men having primary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 13, with the following rewritten paragraph:

-- FIG. 13(b) is a graph showing the LH concentrations on days 0 through 180 for men having secondary hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 16, with the following rewritten paragraph:

-- FIG. 13(c) is a graph showing the LH concentrations on days 0 through 180 for men having age-associated hypogonadism and receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 18, line 19, with the following rewritten paragraph:

-- FIG. 13(d) is a graph showing the LH concentrations on days 0 through 180 for men having hypogonadism of an unknown origin and receiving either 5.0 g/day of AndroGel® (---), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 19, line 1, with the following rewritten paragraph:

-- FIG. 14(a) is a bar graph showing the change in hip BMD for hypogonadal men after 180 days of treatment with 5.0 g/day of AndroGel® (☒), 5.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (wide hatch mark), 10.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (narrow hatch marks), 10.0 g/day of AndroGel® (■), or the testosterone patch (□). --

Please replace the paragraph beginning on page 19, line 4, with the following rewritten paragraph:

-- FIG. 14(b) is a bar graph showing the change in spine BMD for hypogonadal men after 180 days of treatment with 5.0 g/day of AndroGel® (☒), 5.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (wide hatch mark), 10.0 g/day of AndroGel® switched to 7.5 g/day of AndroGel® (narrow hatch marks), 10.0 g/day of AndroGel® (■), or the testosterone patch (□). --

Please replace the paragraph beginning on page 19, line 7, with the following rewritten paragraph:

-- FIG. 15 is a graph showing PTH concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— — — —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 19, line 10, with the following rewritten paragraph:

-- FIG. 16 is a graph showing SALP concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— — — —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 19, line 13, with the following rewritten paragraph:

-- FIG. 17 is a graph showing the osteocalcin concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— — — —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 19, line 16, with the following rewritten paragraph:

-- FIG. 18 is a graph showing the type I procollagen concentrations on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 19, line 19, with the following rewritten paragraph:

-- FIG. 19 is a graph showing the N-telopeptide/Cr ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 20, line 1, with the following rewritten paragraph:

-- FIG. 20 is a graph showing the Ca/Cr ratio on days 0 through 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (- - - -), 10.0 g/day of AndroGel® (— —), or the testosterone patch (——) (by initial treatment group). Normal high and low testosterone levels (ng/dl) are represented by the (— - - — -) line. --

Please replace the paragraph beginning on page 21, line 7, with the following rewritten paragraph:

--FIG. 24(a) is a bar graph showing the change in leg strength on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of

AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□).--

Please replace the paragraph beginning on page 21, line 10, with the following rewritten paragraph:

--FIG. 24(b) is a bar graph showing the change in arm strength on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□).--

Please replace the paragraph beginning on page 21, line 13, with the following rewritten paragraph:

--FIG. 25(a) is a bar graph showing the change in total body mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□).--

Please replace the paragraph beginning on page 21, line 16, with the following rewritten paragraph:

--FIG. 25(b) is a bar graph showing the change in lean body mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□).--

Please replace the paragraph beginning on page 21, line 19, with the following rewritten paragraph:

--FIG. 25(c) is a bar graph showing the change in fat mass on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□).--

Please replace the paragraph beginning on page 22, line 1, with the following rewritten paragraph:

--FIG. 25(d) is a bar graph showing the change in percent body fat on days 90 and 180 for hypogonadal men receiving either 5.0 g/day of AndroGel® (diagonal hatch marks), 7.5 g/day of AndroGel® (horizontal hatch marks), 10.0 g/day of AndroGel® (⊠), or the testosterone patch (□).--

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